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Applicant:	Garrison, *et al.*	Atty Dkt No:	1527.030
Serial No:	10/804,386	Examiner:	D. YABUT
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For: DELIVERY SYSTEMS AND METHODS FOR DEPLOYING EXPANDABLE INTRALUMINAL MEDICAL DEVICES

Mail Stop - Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY AND AMENDMENT

Honorable Sir:

The following comments and amendments are made in response to the non-final Office Action mailed on April 27, 2007, in respect of the above-entitled application for patent. Reconsideration of the application for patent is requested in view of the amendments and remarks made herein.

In response to the subject Office Action, Applicants herein amend the claims and provide remarks regarding the listed rejections.

Amendments to the Specification are not presented in this paper.

Amendments to the Abstract are not presented in this paper.

Amendments to the Drawings are not presented in this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 2.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

The following listing of claims, in which text to be added is underlined and text to be deleted is stricken through, will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A method for delivering and deploying an expandable intraluminal medical device, comprising:

providing a delivery system comprising an elongate member having proximal and distal ends and defining a lumen, the delivery system further comprising an ancillary delivery device at least partially disposed in the lumen and having a means for spacing a portion of the elongate member from a wall surface of a body vessel, said expandable intraluminal medical device circumferentially disposed about a portion of the elongate member;

inserting the distal end of the elongate member into a body vessel;

advancing the distal end of the elongate member through the body vessel and to a desired point of treatment;

spacing a portion of the elongate member from a wall surface of the body vessel at a point distal to said expandable intraluminal medical device by activating the means for spacing;

deploying said expandable intraluminal medical device from the elongate member after the elongate member has been spaced from a wall surface of the body vessel; and

withdrawing the elongate member from the body vessel.

2. (Previously presented) The method for delivering and deploying an expandable intraluminal medical device according to claim 1, wherein the step of spacing a portion of the elongate member from a wall surface of the body vessel comprises spacing a portion of the elongate member that includes said expandable intraluminal medical device.

3. (Canceled)

4. (Currently amended) The method for delivering and deploying an expandable intraluminal medical device according to Claim ~~3~~ 1, wherein the means for spacing comprises a basket formed from at least two wire members

and having expanded and collapsed configurations.

5. (Withdrawn) A method for delivering and deploying an expandable intraluminal medical device according to Claim 1, wherein the elongate member includes a means for spacing a portion of the elongate member from a wall surface of a body vessel.

6. (Withdrawn) A method for delivering and deploying an expandable intraluminal medical device according to Claim 5, wherein the means for spacing comprises a Malecot assembly.

7. (Withdrawn) A method for delivering and deploying an expandable intraluminal medical device according to Claim 5, wherein the means for spacing comprises an inflatable balloon.

8. (Previously presented) The method for delivering and deploying an expandable intraluminal medical device according to Claim 1, wherein the delivery system further comprises a sheath circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal medical device comprises retracting the sheath from a position about the expandable intraluminal medical device.

9. (Canceled)

10. (Canceled)

11. (Currently amended) The method for delivering and deploying an expandable intraluminal medical device according to Claim ~~10~~ 8, wherein the ~~step of~~ activating the means for spacing includes retracting the sheath from a position about the means for spacing.

12. (Previously presented) The method for delivering and deploying an expandable intraluminal medical device according to Claim l, wherein said expandable intraluminal medical device comprises a prosthetic venous valve.

13. (Previously presented) A delivery system, comprising

an elongate member having proximal and distal ends and defining a first lumen,

an expandable intraluminal medical device circumferentially disposed about a portion of the elongate member;

a sheath circumferentially disposed about the elongate member and the expandable intraluminal device, the sheath being movable along the elongate member; and

an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations;

wherein the basket is in the collapsed configuration when disposed in the first lumen and is in the expanded configuration when not disposed in the first lumen.

14. (Previously presented) The delivery system for delivering and deploying an expandable intraluminal medical device according to Claim 13, wherein the at least two wire members comprise flat wire.

15. (Withdrawn) A delivery system for delivering and deploying an expandable intraluminal medical device according to Claim 13, wherein one of the at least two wire members defines two commissural points.

16. (Withdrawn) A delivery system for delivering and deploying an expandable intraluminal medical device according to Claim 13, wherein each of the at least two wire members defines two commissural points.

17. (Withdrawn) A delivery system for delivering and deploying an expandable intraluminal medical device according to Claim 13, wherein the elongate member further defines a second lumen separate from the first lumen.

18. (Previously presented) The delivery system for delivering and deploying an expandable intraluminal medical device according to Claim 13, wherein the expandable intraluminal device comprises a prosthetic venous valve.

19. (Withdrawn) A delivery system, comprising

an elongate member having proximal and distal ends and having a means for spacing a portion of the elongate member from a wall surface of a body

vessel;

a prosthetic valve disposed about a portion of the elongate member and spaced from the means for spacing; and

a sheath circumferentially disposed about the elongate member and over the prosthetic valve.

20. (Withdrawn) A delivery system according to Claim 19, wherein the means for spacing comprises a Malecot assembly.

21. (Withdrawn) A delivery system according to Claim 19, wherein the means for spacing comprises an inflatable balloon.

REMARKS

In the Office Action issued on April 27, 2007, the Examiner:

- rejected claims 1 through 4 under 35 U.S.C. §102(b) as being anticipated by Kirkman (United States Patent No. 6,071,263);
- rejected claims 8 through 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of St. Germain (United States Patent No. 5,534,007);
- rejected claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Pavcnik (United States Published Application No. 20010039450);
- rejected claims 13 and 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Levine (United States Published Application No. 20040087965); and
- rejected claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Pavcnik (United States Published Application No. 20010039450).

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections. Reconsideration of the application for patent is requested.

Preliminary matter – Examiner Interview

As a preliminary matter, the Applicants would like to thank the Examiner for the interview conducted at the Patent and Trademark Office on June 4, 2007. The undersigned attorney and the Examiner discussed the cited references and potential claim amendments in the interview. While no agreement on the claims was reached, the Examiner's suggestions regarding potential amendments for distinguishing the prior art references are considered to be helpful.

Rejection of Claims 1 through 4 under 35 U.S.C. §102

The Examiner rejected Claims 1 through 4 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,071,263 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Kirkman "discloses a method for delivering and deploying an expandable intraluminal device" that includes the steps recited in Claims 1 through 4 of the present application for patent.

The applicants have herein canceled Claim 3, rendering its rejection moot.

The Applicants have herein amended independent Claim 1 in accordance with the Examiner's suggestions to include the ancillary delivery device and to further define the spacing step as occurring "at a point distal to said expandable intraluminal medical device" and "by activating the means for spacing."

Kirkman does not disclose either of these limitations and cannot, therefore, properly serve as an anticipatory reference under 35 U.S.C. §102. Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 1 through 4 in light of the amendment made herein.

Rejection of Claims 8 through 11 under 35 U.S.C. §103

The Examiner rejected Claims 8 through 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Patent No. 5,534,007 to St. Germain *et al.* ("St. Germain"). Specifically, the Examiner indicated that Kirkman "discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device."

The applicants have herein canceled Claims 9 and 10, rendering their rejection moot.

The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 8 through 11.

A *prima facie* case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success. Lastly, the references must teach or suggest all limitations of the claims. (See M.P.E.P.§2143).

The Examiner has failed to establish a *prima facie* case of obviousness at least because the cited references do not teach or suggest all limitations of the claims. Each of Claims 8 through 11 depend from Claim 1, which, as described above, has herein been amended to further define the spacing step as occurring "at a point distal to said expandable intraluminal medical device" and "by activating the means for spacing."

A careful review of St. Germain reveals that it also fails to disclose these limitations. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of any of the rejected claims.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 8 and 11 in light of the amendment made herein.

Rejection of Claim 12 under 35 U.S.C. §103

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 12 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 12 depends from Claim 1, which, as described above, has herein been amended to further define the spacing step as occurring "at a point distal to said expandable intraluminal medical device" and "by activating the means for spacing." As detailed above, Kirkman fails to disclose these limitations.

A careful review of Pavcnik reveals that it also fails to disclose these limitations. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of any of the rejected claims. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 8 and 11 in light of the amendment made herein.

Rejection of Claims 13 and 14 under 35 U.S.C. §103

The Examiner rejected Claim 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20040087965 to Levine ("Levine"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 13 and 14 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 14 depends from Claim 13 and, therefore, includes all limitations of that claim. Kirkman fails to disclose the structural relationship between the elements that is required by Claim 13. Specifically, Kirkman does not disclose "an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations," the first lumen being defined by "an elongate member" that, in turn, is disposed within a sheath that is "circumferentially disposed about the elongate member."

A careful review of Levine reveals that it also fails to disclose such a structural relationship. As such, it fails to cure the defect of Kirkman and, as a

result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

The Applicants note that the Examiner relied on Levine for disclosure of flat wire members. This aspect of the disclosure is irrelevant, however, considering the defect of Kirkman and Levine's lack of a cure for that defect. Accordingly, the Applicants have not herein commented on the Examiner's characterization of Levine as disclosing flat wire members.

Applicants respectfully assert that the rejection of Claim 14 is improper and request its reconsideration.

Rejection of Claim 18 under 35 U.S.C. §103

The Examiner rejected Claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 18 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 18 depends from Claim 13 and, therefore, includes all limitations of that claim. As detailed above, Kirkman fails to disclose the structural relationship between the elements that is required by Claim 13. Specifically, Kirkman does not disclose "an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations," the first lumen being defined by "an elongate member" that, in turn, is disposed within a sheath that is "circumferentially disposed about the elongate member."

A careful review of Pavcnik reveals that it also fails to disclose such a structural relationship. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

Applicants respectfully assert that the rejection of Claim 18 is improper and request its reconsideration.

CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the April 27, 2007 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

/J.Matthew BUCHANAN,Reg.No. 47,459/

J. Matthew Buchanan
Reg. No. 47,459
DUNLAP, CODDING and ROGERS, P.C.
Customer No. 42715
P.O. Box 16370
Oklahoma City, Oklahoma 73113
Telephone:(405) 607-8600
Facsimile:(405) 607-8686
E-Mail: matt_buchanan@okpatents.com
Web Site: www.okpatents.com

Attorney for Applicants